DEPARTMENT OF HEALTH .. HUMAN SERVICES
Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

95P-0152

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Christopher R. Kaup, Esq.
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2700 North Central Avenue
Suite 1500
Phoenix, Arizona 85012-1941

Dear Dr. Kaup:

Thank you for your citizen's petition and your supplemental submission on behalf of Steri-Lube, Inc. We are sorry for the delay in responding to your questions. We have considered your request that the Food and Drug Administration (FDA) make certain that the manufacturers of lubricants used with air driven dental handpieces comply with the Safe Medical Devices Act (SMDA) and existing regulations.

You presented many interesting points in your supplemental submission about the need for sterile and non-toxic lubricants for dental handpieces. We recognize that problems could arise when lubricants remain on the handpieces. We also recognize the potential problem of cross-contamination when separate delivery systems are not used for the pre- and post-sterilization procedures.

The Center for Devices and Radiological Health (CDRH) is aware of these concerns and is gathering information on the current manufacturing processes in place for these products and any other product-related issues pertinent to these problems. CDRH will do what is necessary to regulate this industry and, ultimately, to protect the health of dental patients in the United States.

Handpiece lubricants are often reviewed as a part of the premarket notification application (510(k)) for individual handpieces. Therefore some lubricants would not have separate 510(k) applications. We also recognize that all manufacturers of handpiece lubricants do not have 510(k) applications for their products. The Office of Compliance is working to resolve this matter.

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ANSI

CDRH is planning to convene a Dental Products Advisory Panel meeting before the end of the year. The Panel will discuss the reclassification of dental handpieces and the subsequent regulation of both the lubricants and the handpieces. Members of your law firm and any interested members of Steri-Lube, Inc. are welcome to attend this meeting. You will find an announcement of the Panel meeting in the ***Federal Register*** and on CDRH's home page. The address for our home page is:

http://www.fda.gov/cdrh/devices.html

For meeting dates and other information, you may also call the FDA advisory committee information line at 1-800-741-6138 and press 12518 for the Dental Products Panel specifically.

If you have any questions regarding this matter, please contact Ms. Angela Blackwell at 301-827-5283, Ext. 119.

Sincerely yours,

Elizabeth D. Jacobson

Elizabeth D. Jacobson, Ph.D.
Deputy Director for Science
Center for Devices and
Radiological Health